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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.

S2003/0304

Date of Filing

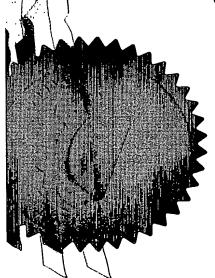
22 April 2003

Applicant

PATRICK LEAHY, an Irish citizen of 14 Hume

Street, Dublin 2.

Dated this 21 day of April 2004.



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An officer authorised by the Controller of Patents, Designs and Trademarks.

Application No.

# REQUEST FOR THE GRANT OF A PATENT PATENTS ACT, 1992

The Applicant named herein hereby request

- $\simeq$  the grant of a patent under Part II of the Act
- $\underline{X}$  the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. APPLICANT

Name

**Patrick Leahy** 

Address

14 Hume Street, Dublin 2.

Description/Nationality

Irish

2. TITLE OF INVENTION

"A Surgical Device"

3. DECLARATION OF PRIORITY ON BASIS OF PREVIOUSLY FILED APPLICATION FOR SAME INVENTION (SECTIONS 25 & 26)

Previous filing date

Country in or for

Filing No.

which filed

4. **IDENTIFICATION OF INVENTOR(S)** 

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

- 1. Patrick Leahy
- 2. .

#### **Address**

- 1. 14 Hume Street, Dublin 2.
- 2.
- 5. STATEMENT OF RIGHT TO BE GRANTED A PATENT (SECTION 17(2)(B))

By virtue of the Applicant being the Inventor.

Contd./...

#### 6, ITEMS ACCOMPANYING THIS REQUEST - TICK AS APPROPRIATE

- (i)  $\underline{X}$  prescribed filing fee (£60.00)
- (ii)  $\simeq$  specification containing a description and claims
  - X specification containing a description only
  - X Drawings referred to in description or claims
- (iii) ~ An abstract
- (iv) ~ Copy of previous application(s) whose priority is claimed
- (v) ~ Translation of previous application whose priority is claimed
- (vi)  $\simeq$  Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

#### 7. DIVISIONAL APPLICATION

The following information is applicable to the present application which is made under Section

Earlier Application No: ~ Filing Date: ~

#### 8. AGENT

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The following is authorised to act as agent in all proceedings connected with the obtaining of a Patent to which this request relates and in relation to any patent granted -

F. R. KELLY & CO.

at their address as recorded for the time being in the Register of Patent Agents

#### 9. ADDRESS FOR SERVICE (IF DIFFERENT FROM THAT AT 8)

Patrick Leahy F. R. KELLY & CO.

EXECUTIVE

Date: April 22, 2003

The present invention relates to a surgical device and, in particular, to a device for facilitating hand-assisted surgical procedures, such as through an abdominal wall incision.

Known surgical methods involve filling the surgical site, for example the abdominal cavity, with a gas, such as CO<sub>2</sub> to expand the cavity and facilitate the surgical procedure. However, since the gas continually leaks from the cavity, large volumes of the gas have to be continually pumped into the abdominal cavity throughout the procedure. The known method is therefore costly and complex.

In addition, since the CO<sub>2</sub> is introduced directly into the abdominal cavity, adverse reactions are commonly encountered, thereby further complicating the surgical procedure.

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The present invention has been made from a consideration of the disadvantages associated with this known surgical method and in order to provide a surgical device which overcomes such disadvantages.

According to the invention there is provided a surgical device comprising a flexible sleeve having open front and rear ends and one or more inflatable balloons secured to the outer surface of the sleeve adjacent the front end thereof.

Preferably, the flexible sleeve is substantially cylindrical and transparent.

Preferably, the device comprises a plurality of such balloons secured in side by side disposition around the front end of the sleeve. Alternatively, the device may comprise a single tubular balloon disposed around the front end of the sleeve.

10 Preferably, each such balloon is connectable to a fluid supply means via a tube section. Preferably, a connector is secured to the outer surface of the sleeve, the connector being adapted to fluidly connect the tube sections to a fluid supply means.

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Preferably, a ring is secured to the rear end of the sleeve. Preferably, the ring is rigid and is adapted to hold the rear end open. Preferably, the ring is adapted to receive a sealing cap for sealing the open rear end of the sleeve.

Preferably, a flexible collar is secured to the inner surface of the sleeve at the front end thereof and underlying the inflatable balloons. Preferably, the collar is adapted to fit closely around and be lightly clamped against a wrist in use.

Preferably, a lubricant is provided on the inner surface of the sleeve. Preferably, an elongate strap is secured between two locations adjacent the front end of the sleeve.

The invention will now be described further, by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a front perspective view of a surgical device of the invention with deflated balloons; and

Fig. 2 is a rear perspective view of the surgical device of figure 1 with the balloons inflated.

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Referring to figure 1, a surgical device 1 of the invention comprises a substantially cylindrical flexible sleeve 2 having open front and rear ends 4, 6. The flexible sleeve 2 is typically transparent to facilitate the surgical procedure.

A plurality of inflatable balloons 8 are secured in side by side disposition to the outer surface of the sleeve around the front end 4 thereof. Typically, the balloons extend along about one quarter to one third the length of the sleeve.

It will be appreciated that the balloons may take any suitable form and, for example, a single tubular balloon may be provided on the front end of the sleeve instead of the plurality of individual balloons 8.

Referring to figure 2, each balloon 8 is connected to a fluid supply means, such as a pump, via a tube section 10 joined to a connector 12 secured to the outer surface of the sleeve. The tube sections 10 extend through location pockets 14 provided at suitable locations around the outer surface of the sleeve 2. The

connector 12 fluidly connects the tube sections 10 to the pump via a supply tube 16. Inflation of the balloons is shown in figure 2.

In order to facilitate insertion of a surgeon's arm into the device of the invention, a rigid ring 18 is secured to the rear end 6 of the sleeve to hold the rear end open. In addition, the ring is adapted to receive a sealing cap (not shown) for sealing the open rear end of the sleeve, when required.

Typically, the sleeve is provided with a flexible collar (not shown) secured to the inner surface of the sleeve at the front end 6 thereof and underlying the inflatable balloons. The collar fits closely around the surgeon's wrist in use and prevents it being restricted upon inflation of the balloons.

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The collar also prevents the ingress or egress of gasses or other substances through the sleeve, past the surgeon's wrist, into or out of the surgical cavity.

In use, a surgeon inserts his arm into the sleeve 2 through the rear end 6 until the hand projects from the 25 front end 4. The inflatable balloons 8 typically overlie the surgeon's wrist. A small incision is made at the required site, for example in the patient's abdomen.

The surgeon's arm with the sleeve thereon is passed through the incision into the patient's abdominal cavity. Typically, the sleeve is only inserted a distance just beyond the inflatable balloons.

At this point, one or more, typically all, of the balloons are inflated by any suitable means, for example a pump or the like, thereby forming a cavity around the surgeon's hand. A fibre optic camera or the like may be inserted into the cavity to facilitate the surgical procedure.

At the end of the procedure, the balloons are deflated so that the surgeon's arm and the device are easily removed.

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Typically, a lubricant is provided on the inner surface of the sleeve to facilitate ease of insertion and removal of the surgeon's arm. Such a lubricant is particularly beneficial if the surgeon needs to remove his arm during an operation, since the lubricant ensures that the sleeve is not inadvertently drawn partially or fully out of the surgical cavity as the arm is removed.

The surgical device may include an elongate strap secured between two locations adjacent the front end of the sleeve, the strap being adapted to locate in use around the thumb of the surgeon's hand to retain the device in position on the hand during use.

When using the surgical device of the invention, it may exceptionally be desirable to add additional insufflation gas directly into the surgical cavity. In such a case, when the surgeon desires to remove his arm during surgery, the sealing cap is secured to the rigid ring 18 at the rear end of the sleeve, thereby ensuring

that the insufflation gasses do not leak from the surgical cavity through the sleeve.

When the surgeon's arm is located within the sleeve, the collar is lightly clamped against the surgeon's wrist, thereby preventing the escape of any such insufflation gasses. In addition, the collar prevents undue pressure from being applied to the surgeon's wrist by the inflated balloons, which could otherwise interfere with the movement and blood flow of the surgeon's hand.

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avoided.

With the surgical device of the invention, the insufflation gasses are maintained within the balloons. Thus, the cost and complexity associated with the continual leakage of gas from the cavity in the previous surgical method are avoided. Furthermore, adverse reactions and complications associated with introducing CO<sub>2</sub> directly into the abdominal cavity are

It will be appreciated that the present invention is not intended to be restricted to the details of the above embodiment, which is described by way of example only.

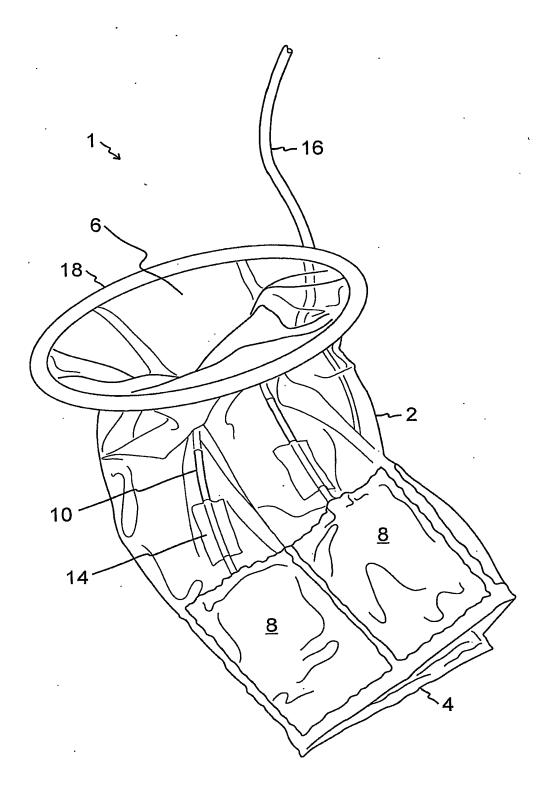


Fig. 1

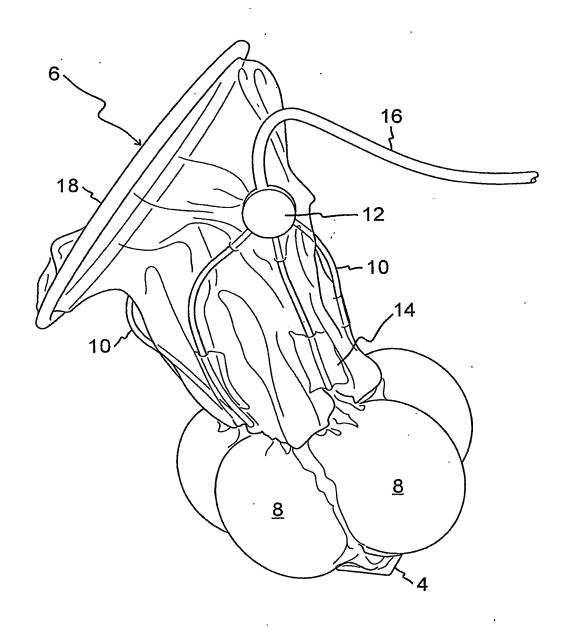


Fig. 2

PCT/EP2004/004381					
Box No. VIII (i) DECLARATION: IDENTITY OF THE INVENTOR  The declaration must conform to the standardized wording provided for in Section 211; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (i). If this Box is not used, this sheet should not be included in the request.					
Declaration as to the identity of the inventor (Rules 4.17(i) and 51bis.1(a)(i)):					
in relation to this international application (i) Patrick Leahy of 14 Hume Street, Dublin 2, Ireland, is the inventor of the subject matter for which protection is sought by way of this international application					
(ii) this declaration is made for the purposes of : (a) all designations					

This declaration is continued on the following sheet, "Continuation of Box No. VIII (i)".

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'n		DATENT

#### Box No. VIII (ii) DECLARATION: ENTITLEMENT TO APPLY FOR AND BE GRANTED A PATENT

The declaration must conform to the standardized wording provided for in Section 212; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (ii). If this Box is not used, this sheet should not be included in the request.

Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate:

in relation to this international application, Patrick Leahy is entitled to apply for and be granted a patent by virtue of the following:

(i) Patrick Leahy of 14 Hume Street, Dublin 2, Ireland, is the inventor of the subject matter for which protection is sought by way of this international application

This declaration is made for the purposes of :
(a) all designations

This declaration is continued on the following sheet, "Continuation of Box No. VIII (ii)".

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### Box No. VIII (iii) DECLARATION: ENTITLEMENT TO CLAIM PRIORITY

The declaration must conform to the standardized wording provided for in Section 213; see Notes to Boxes Nos. VIII. (i) to (v) (in general) and the specific Notes to Box No. VIII (iii). If this Box is not used, this sheet should not be included in the request.

Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application specified below, where the applicant is not the applicant who filed the earlier application or where the applicant's name has changed since the filing of the earlier application (Rules 4.17(iii) and 51bis.1(a)(iii)):

in relation to this international application, Patrick Leahy is entitled to claim priority of earlier application No. S2003/0304 by virtue of the following:

(i) the applicant is the inventor of the subject matter for which protection was sought by way of the earlier application

(ix) this declaration is made for the purposes of :

(a) all designations

1	This declaration is continued on the following sheet,	"Continuation of Box No."	VΠΙ (iii)".
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Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America) The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

## Declaration of inventorship (Rules 4.17(iv) and 51bis.1(a)(iv))

for the purposes of the designation of the United States of America:				
I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.				
This declaration is directed to the international application of which it	forms a part (if filing declaration with application).			
This declaration is directed to international application No. PCT/				
I hereby declare that my residence, mailing address, and citizenship ar	re as stated next to my name.			
I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.				
Prior Applications:				
I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.				
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.				
Name: Patrick Leahy				
Residence:				
Mailing Address: 14 Hume Street, Dublin 2, Ireland				
Citizenship: Irish  Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	Date: 2t/54/2307  (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)			
Name:				
Residence:				
Mailing Address:				
Citizenship:				
Inventor's Signature:	Date:			
This declaration is continued on the following sheet, "Continuation of the following sheet,"	on of Box No. VIII (iv)".			